DEPARTMENT OF HEALTH & HUMAN SERVICES T2095M

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-54082

October 1, 1998

Robert N. Hansen
3H Cattle Company
1230 Otis
Corcoran, California 93212

WARNING LETTER

Dear Mr. Hansen:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on September 16, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. Our investigation revealed that you administered Micotil 300 (tilmicosin) to a cow on August 14, 1998. You delivered this cow (identified by USDA laboratory report number 273569) to the owner on August 24, 1998. The owner delivered the cow for sale for slaughter. This cow was delivered for introduction into interstate commerce and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of tilmicosin in the kidney tissue at 46.90 parts per million (ppm), in the liver tissue at 10.10 ppm, and in the muscle tissue at 19.30 ppm. A tolerance level for tilmicosin in the edible tissues of cows has been established at 1.20 ppm in the liver.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies to this particular residue, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. You lack an adequate system for assuring that animals to which medication is administered, such as tilmicosin, have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

You are adulterating the drug Micotil 300 brand tilmicosin phosphate within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with its approved labeling directions. The directions specify that animals intended for human consumption must not be treated within twenty-eight days of being slaughtered. Failure to adhere to the prescribed withdrawal time is the cause of the residues in the cow you delivered.

You are frequently the individual who delivers, or offers for introduction into interstate commerce, cows and calves intended for slaughter for food. As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act if such animals are adulterated. To avoid future illegal residue violations, you should take precautions such as implementing a system to withhold medicated animals from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal, then it should clearly be identified and sold or returned to a grower as a medicated animal.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale at an auction yard where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act. You are also responsible for violations of the Act when you deliver animals without informing the recipients of the medication status of those animals you have medicated.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, P.O. Box 169, Fresno, California 93707.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District